UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

RYAN BERGSTRESSER,	:	**CIVIL ACTION NO. 3:12-1464**
Plaintiff	:	
v.	:	**(JUDGE MANNION[1])**
BRISTOL-MYERS SQUIBB COMPANY[2],	:	
Defendant	:	

M E M O R A N D U M

Pending before the court is the defendant's motion for judgment on the pleadings. (Doc. No. 9)[3]. Based upon the court's review of the motion and related materials, the defendant's motion for judgment on the pleadings will be granted in part and denied in part. Further, the plaintiff will be given the opportunity to file an amended complaint in order to cure the deficiencies of his complaint as more fully discussed herein.

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[1]The instant action was originally assigned to the Honorable A. Richard Caputo. By verbal order, on January 7, 2013, the matter was reassigned.

[2]The defendant has provided that it was incorrectly designated "Bristol-Meyers Squibb Company" in the complaint. The correct designation is used herein.

[3]The motion further requests oral argument. However, the court finds that the briefing filed by the parties is sufficient to decide the motion and that oral argument is therefore unnecessary at this time.

I. PROCEDURAL HISTORY

By way of relevant background, the plaintiff filed the instant action on July 5, 2012, in the Court of Common Pleas of Lackawanna County, in which he alleges that he suffered personal injuries as a result of taking the prescription medication Abilify. The plaintiff sets forth claims of negligence, strict liability and breach of implied warranty in his complaint. (Doc. No. 1, Ex. 1). On July 30, 2012, the defendant removed the action to this court based upon diversity jurisdiction. (Doc. No. 1). On the same day, the defendant filed an answer to the plaintiff's complaint. (Doc. No. 3).

On September 7, 2012, the defendant filed the instant motion for judgment on the pleadings, (Doc. No. 9), along with a brief in support thereof, (Doc. No. 10). The plaintiff filed an opposing brief on September 24, 2012. (Doc. No. 12). On October 11, 2012, the defendant filed a reply brief. (Doc. No. 13). On December 31, 2012, the defendant filed a notice of supplemental authority in support of its motion. (Doc. No. 14).

II. LEGAL STANDARD

The standard for deciding a motion for judgment on the pleadings pursuant to Rule 12(c) is identical to that for deciding a motion to dismiss pursuant to Rule 12(b)(6). Turbe v. Gov't of V.I., 938 F.2d 427, 428 (3d Cir. 1991). In deciding the defendant's motion, the court must read the complaint in the light most favorable to the plaintiff and all well-pleaded, material

allegations in the complaint must be taken as true. Estelle v. Gamble, 429 U.S. 97 (1976). However, the court need not accept inferences drawn by the plaintiff if they are unsupported by the facts as set forth in the complaint. See California Pub. Employee Ret. Sys. v. The Chubb Corp., 394 F.3d 126, 143 (3d Cir. 2004) (citing Morse v. Lower Merion School Dist., 132 F.3d 902, 906 (3d Cir. 1997)). The court also need not accept legal conclusions set forth as factual allegations. Bell Atlantic Corp. v. Twombly, 550 U.S. 554, 555 (2007) (citing Papasan v. Allain, 478 U.S. 265, 286 (1986)).

A viable complaint must include "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 554 (rejecting the traditional 12(b)(6) standard set forth in Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). "Factual allegations must be enough to raise a right to relief above the speculative level." Id. at 555. See also Ashcroft v. Iqbal, 556 U.S. 662 (2009) (holding that, while the complaint need not contain detailed factual allegations, it must contain more than a "formulaic recitation of the elements" of a claim and must state a claim that is plausible on its face) (quoting Bell Atlantic Corp. v. Twombly, supra, and providing further guidance on the standard set forth therein).

In deciding the defendant's motion, the court should generally consider only the allegations contained in the complaint, the exhibits attached to the complaint, matters of public record, and "undisputably authentic" documents which plaintiff has identified as the basis of his claim. See Pension Benefit

Guarantee Corp. v. White Consolidated Industries, Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).

III. DISCUSSION

The following allegations are taken from the plaintiff's complaint and are accepted as true for purposes of the instant motion. At all material times, the defendant was engaged in the business of manufacturing, compounding, packaging, labeling and distributing the prescription drug Abilify.

The plaintiff was prescribed Abilify by his treating psychiatrist. On or about July 30, 2010, the plaintiff's dosage of Abilify was increased from 10 mg to 15 mg. The plaintiff began to have immediate side affects as a result of the increased dosage, including symptoms of dystonia[4].

The plaintiff claims that the defendant is liable to him in negligence, (Count I); that the defendant is strictly liable as a matter of law under the provisions of the Restatement (Second) of Torts, §402A, (Count II); and that the defendant is liable to him for breach of implied warranties, (Count III).

In its motion for judgment on the pleadings, the defendant argues that any claims by the plaintiff for strict liability and breach of implied warranty are

[4]Dystonia - Prolonged involuntary muscular contractions that may cause twisting of body parts, repetitive movements, and increased muscular tone. These movements may be in the form of rhythmic jerks. Taber's Cyclopedic Medical Dictionary 654 (20th ed. 2005).

not cognizable under Pennsylvania law in light of the Pennsylvania Supreme Court's decision in Hahn v. Richter, 673 A.2d 888 (Pa. 1996)[5] and its progeny.

In considering the defendant's argument, Pennsylvania law recognizes three types of defects that can give rise to a strict liability claim: a design defect, a manufacturing defect, and a warning defect[6]. Phillips v. A-Best Prods. Co., 665 A.2d 1167, 1170 (Pa. 1995).

In Hahn, the Pennsylvania Supreme Court adopted comment k to Section 402A of the Restatement (Second) of Torts which provides, in relevant part, that "[t]here are some products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and provides that such products, "properly prepared, and accompanied by proper directions and warning, [are] not defective . . . [or] unreasonably dangerous." Applying comment k, the Hahn court concluded that a plaintiff cannot recover under the strict liability theory in failure to warn suits against a prescription drug manufacturer. Hahn, 673 at 890-91. Instead, the Hahn court held that a plaintiff may only recover for a failure to warn under

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[5]Jurisdiction in this matter rests on the diversity of the parties. 28 U.S.C. §1332(a). A federal court sitting in diversity must apply the substantive law of the state in which it sits. Erie R.R. Co. V. Tompkins, 304 U.S. 64, 78 (1938). As such, Pennsylvania law applies to this case.

[6]The plaintiff has not specified in his complaint which type of defect he bases his strict liability claim upon, simply labeling his claim as "Strict Liability in Torts."

the standard set forth in Section 388 of the Restatement (Second) of Torts, which limits recovery in failure to warn cases to those circumstances in which the manufacturer "fails to exercise reasonable care" to warn the consumer, i.e., in negligence. Id.

Subsequent to Hahn, the Pennsylvania Superior Court explained that "[w]ith our Supreme Court's adoption of comment k, a design defect claim for strict liability is [also] not cognizable under Pennsylvania law when it is asserted against a manufacturer of prescription drugs." Lance v. Wyeth, 4 A.3d 160, 165 (Pa.Super. 2010), *appeal granted on other grounds*, 15 A.3d 429 (Pa. 2011).

Some "Pennsylvania and federal courts have interpreted Hahn broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs, including manufacturing defect claims. Salvio v. Amgen, Inc., 810 F.Supp.2d 745, 755-56 (W.D.Pa. 2011) (citations omitted). However, the Pennsylvania Superior Court has recently clarified that a plaintiff may bring a strict liability cause of action against a drug manufacturer for a manufacturing defect claim. Doughtery v. C.R. Bard, Inc., 2012 WL 2940727, *4 (E.D.Pa., July 18, 2012) (citing Lance, supra.). See also Daniel v. Wyeth Pharmaceuticals, Inc., 15 A.3d 909 (Pa.Super. 2011) (citations omitted)[7].

[7]In discussing the Lance opinion, the court in Daniel provided that a failure to warn claim would be available as a strict liability cause of action but, (continued...)

In light of the above, although it is unclear which strict liability claim(s) the plaintiff is attempting to bring, any strict liability claim brought by the plaintiff for failure to warn or design defect are barred by Hahn and its progeny. However, to the extent that the plaintiff attempts to bring a strict liability claim based upon a manufacturing defect, this claim would not be barred.

That being said, the defendant argues that, to the extent the court finds the plaintiff's claim for strict liability based upon a manufacturing defect is a viable claim, the allegations in the plaintiff's complaint are insufficient. Here, a manufacturing defect claim is essentially a claim "that something went awry in the manufacturing process . . . [and] the finder of fact need only compare the product that caused the injury with other products that were manufactured according to specifications." Dambacher v. Mallis, 485 A.2d 408, 426 (Pa.Super. 1984). In order to state a claim for strict liability based upon manufacturer's defect under Pennsylvania law, the plaintiff must show that: (1) the product was defective; (2) the defect was the proximate cause of the plaintiff's injuries; and (3) the defect causing the injury existed when the

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[7](...continued)
citing to Hahn, stated that, if a plaintiff asserts a failure to warn claim, strict liability would not be imposed upon the drug manufacturer, and instead the claim would be analyzed and adjudicated in accordance with the negligence standard contained in the Restatement (Second) of Torts, §388. As indicated, the decision in Hahn takes failure to warn claims out of the realm of strict liability.

product left the seller's hand. Soufflas v. Zimmer, Inc., 474 F.Supp.2d 737, 749 (E.D.Pa. 2007) (citing Pavlik v. Lane Limited/Tobacco Exporters Int'l, 135 F.3d 876, 881 (3d Cir. 1998)). "A product will be deemed defective only if it 'left the supplier's control lacking any element necessary to make it safe for its intended use or possessing any feature that renders it unsafe for the intended use.'" Commonwealth Dep't. of General Services v. U.S. Mineral Products Co., 927 A.2d 717, 725 (Pa.Cmwlth. 2007) (quoting Azzarello v. Black Bros. Co., Inc., 391 A.2d 1020 (1978)).

In this case, the court agrees that the plaintiff has failed to set forth factual allegations sufficient to state a claim for strict liability based upon a manufacturing defect. Relevant to this claim, the plaintiff alleges in his complaint only that he ". . . purchased Abilify in essentially the same condition as when it left the manufacturers plant, . . ."; that the Abilify purchased by the plaintiff ". . . was defective and unreasonable (sic) dangerous when sold by the Defendant, Bristol-Meyers (sic), and the Defendant is strictly liable for the injuries arising from its manufacture, . . ." and "[a]s a result of the actions by Defendant, Bristol-Meyers (sic), as aforementioned, the Plaintiff, Ryan Bergstresser, sustained serious and permanent injuries . . ." These allegations are vague and conclusory, at best, and do not meet the pleading requirements of Twombly and Iqbal. As such, they are insufficient to properly allege a strict liability claim based upon manufacturer's defect.

To the extent that the defendant seeks judgment as a matter of law on

the plaintiff's breach of implied warranty claims, "the theories of strict liability and breach of the implied warranty of merchantability are parallel theories of recovery, one in contract and the other in tort." Doughtery, 2012 WL 2940727 at *7 (internal quotations omitted). As such, any claim by the plaintiff under a theory of breach of the implied warranty of merchantability or breach of the implied warranty of fitness for a particular purpose would be barred under Pennsylvania law to the extent that they are based on a design defect or failure to warn, but would be allowed if based on a manufacturing defect.

Here, again, however, the plaintiff has only set forth bare allegations in support of his claim for breach of implied warranty. Specifically, relevant to the breach of implied warranty based upon a manufacturing defect, the plaintiff alleges, "[a]s a result of the manufacturing and sale of Abilify by Defendant, Bristol-Meyers (sic), there arose certain implied warranties running from the Defendant . . . to the Plaintiff as a purchaser and to the Plaintiff as a user of the drug"; [a]mong the implied warranties made by the Defendant . . . to the plaintiff were that: . . . (iv) Abilify was not defective"; "[n]otwithstanding the above mentioned warranties and the knowledge or implied knowledge of the ordinary purposes for which the drug will be used, possessed by the Defendant . . . Abilify was defective when it left the hands of the Defendant and therefore was unmerchantable and unsuitable for the ordinary and particular purpose for which it was used." These allegations are insufficient to survive the pleading requirements set forth in Twombly and Iqbal which,

while not requiring fact pleading, do require something more than bare conclusory allegations.

The defendant next argues that the plaintiff's negligence claim does not satisfy the pleading requirements of Twombly and Iqbal and should therefore be dismissed. Specifically, the defendant argues that the plaintiff's complaint simply alleges that the plaintiff took Abilify and that he later developed symptoms of dystonia and increased depression. The defendant argues that, without specifying what type of negligence claim he is pursuing, the plaintiff simply provides a list of nine generalized alleged breaches by the defendant. With no guidance as to the theory or theories upon which the plaintiff is proceeding, the defendant argues as to each of the potential claims, including negligent failure to warn and negligent design/manufacture defect[8], why the plaintiff's allegations are insufficient.

In response to the defendant's motion, the plaintiff does nothing more than to state that he "has plead more than sufficient facts as [he] engaged in fact pleading under the requirement of the state court level in the Commonwealth of Pennsylvania." He further argues that ". . . dismissal under a Motion for Judgment on the Pleadings for failure to specifically plead the *negligent failure to warn* and strict liability claim[s] must be dismissed."

[8]Defendant argues that Pennsylvania does not recognize any potential claims by the plaintiff for negligent failure to test or negligent marketing. (Doc. No. 10, p. 11).

(Emphasis added).

Although it is not completely clear from his complaint, it appears from the plaintiff's brief opposing the defendant's motion that he is only attempting to proceed on a negligent failure to warn theory. Under Pennsylvania law, the plaintiff must show: "that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries." Salvio v. Amgen, Inc., 810 F.Supp.2d 745, 752-53 (W.D. Pa. 2011) (citing Parkinson v. Guidant Corp., 315 F.Supp.2d 741, 749 (W.D.Pa. 2004)). See also Dauphin Deposit Bank & Trust v. Toyota, 596 A.2d 845, 849-50 (Pa.Super. 1991)); Oddi v. Ford Motor Co., 234 F.3d 136, 144 (3d Cir. 2000). Further, in a negligence claim based upon failure to warn, the plaintiff must prove that the manufacturer was at fault. Id. (citing Parkinson, 315 F.Supp.2d at 749).

Where a case involves a negligent failure to warn regarding a pharmaceutical drug, the Pennsylvania courts have adopted the "learned intermediary doctrine" stating:

> [T]he manufacturer of a prescription drug known to be dangerous for its intended use, has a duty to exercise reasonable care to inform those for whose use the article was supplied of the facts which make the product likely to be dangerous. However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer. This is so because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers

> or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug. Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate.

Id. (citing Daniel v. Wyeth Pharms., Inc., 15 A.3d 909, 924 (Pa.Super. 2011) (quoting Taurino v. Ellen, 579 A.2d 925, 927 (Pa.Super. 1990), *appeal denied*, 589 A.2d 693 (Pa. 1991)). Where the manufacturer provides proper warning to a consumer's physician, it will have discharged its duty to the consumer.

Relevant to his negligent failure to warn claim, the plaintiff in this case alleges that the "[d]efendant failed to adequately warn of the dangers which it knew or should have known that Abilify posed to persons with neurolglial (sic) disorders" and "[d]efendant placed Abilify into the stream of commerce for sale and recommended its use to physicians and others without warning physicians and others of the risks associated with the use of the drug." The plaintiff does not address the warnings provided on the Abilify label, nor does he point to any deficiencies in the labeling[9]. Further, the plaintiff fails to

[9]The defendant has provided a copy of the November 2009 Abilify label, which may be considered as a matter of public record by the court for purposes of the instant motion for judgment on the pleadings. See Salvio, 810 (continued...)

indicate what warning should have been given or that any alternative warning would have prevented his physician from prescribing him Abilify. See Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa.Super. 1996); Lineberger v. Wyeth, 2005 WL 1274458, *3 (Pa.Ct.Com.Pl. May 23, 2005). Thus, the allegations of the plaintiff's complaint are insufficient to state a claim for negligent failure to warn.

To the extent that the court finds his complaint insufficient, the plaintiff asks the court to afford him the opportunity to amend his complaint pursuant to Fed.R.Civ.P. 15(a)(2) to include more specific allegations. Under Federal Rule of Civil Procedure 15(a), a party may amend its pleading after receiving leave of court, and the court should freely give leave when justice so requires. Fed.R.Civ.P. 15(a)(2). Moreover, "the Supreme Court has encouraged generous application of this rule generally, allowing leave to amend in the absence of evidence of undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowing the amendment [or] futility of amendment." Deen-Mitchell v. Lappin, 2012 WL 74900, *4 (M.D. Pa. Jan. 10, 2012) (citing United States v. Verdekal, 2011 U.S. Dist. LEXIS 149616, at*7 (M.D.Pa. Dec. 30, 2011) (citations and internal quotation marks omitted)). Given this, the court will grant the plaintiff's request

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[9](...continued)
F.Supp.2d at 750-51.

to amend his complaint to cure the deficiencies of his complaint as discussed herein.

IV. CONCLUSION

On the basis of the foregoing, the defendant's motion for judgment on the pleadings, (Doc. No. 9), will be granted in part and denied in part as discussed above. Further, the plaintiff will be given an opportunity to amend the deficiencies of his complaint as discussed above. An appropriate order shall follow.

s/ *Malachy E. Mannion*
MALACHY E. MANNION
United States District Judge

Date: April 24, 2013

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